UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 09-10857-RGS

OTIS WATKINS, and McKINLEE PRUETT, Individually and as Representatives of a Proposed Class

٧.

OMNI LIFE SCIENCE, INC., Successor to Apex Surgical, LLC

MEMORANDUM AND ORDER ON DEFENDANT'S MOTION TO DISMISS

March 9, 2010

STEARNS, D.J.

Plaintiffs Otis Watkins and McKinlee Pruett are recipients of the Apex Model Replacement Hip (Apex Hip), designed, marketed, and sold by defendant Omni Life Science, Inc. (Omni), the successor to Apex Surgical, LLC (Apex). Although neither plaintiff alleges an Apex Hip malfunction, they claim that the relatively high rate of failure of the Apex Hip places them and members of the proposed class at serious risk of future harm. The failure rate is also alleged to have diminished the market value of their hip implants and those of the putative class members. Plaintiffs claim they "would not have selected the Defective Hip over other alternative devices but for the uniform representations made by Defendant." Compl. ¶¶ 51, 54. Based on the alleged Apex Hip defects and Omni's sales representations, plaintiffs assert claims for breach of implied warranty (Count I), breach of contract (Count II), unjust enrichment and constructive trust (Count III), violations of the

¹The proposed class does not include recipients of Apex Hip implants who have experienced an actual failure or malfunction.

Massachusetts consumer protection statute, Mass. Gen. Laws ch. 93A (Count IV), and violations of the consumer protection laws of all other states (Count V).² On July 24, 2009, Omni filed a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6). A hearing on the motion was held on November 9, 2009.

BACKGROUND

The facts, viewed in the light most favorable to plaintiffs as the non-moving parties, are as follows. The Apex Hip was first marketed in 2000. Failures of the Apex Hip began to be reported in 2004. Plaintiffs identify the following defects in design as the explanation for the failures:

a) the use of a plug instead of a bolt to connect the stem to the neck; and b) the use of an alignment pin with too small of a diameter (.125"). When used as directed, such defects in the Apex Modular Hip Stem caused the product to have insufficient torsion strength due to a shearing of the alignment pin, leading to a deficient modular connection.

Compl. ¶ 34. In 2005, Apex was acquired by Omni. By 2006, Omni personnel had redesigned the Apex Hip in response to the reports of failure.

Before the Apex Hip was redesigned, 1,568 patients received an Apex Hip implant. Among these 1,568 recipients, sixty-five Apex Hips (to date) have failed (a failure rate of 4.15 percent). According to plaintiffs, this rate is sixteen times higher than the 0.27 percent failure rate of other replacement hips.³ See Opp'n at 16. However, plaintiffs' Apex Hip

²The named plaintiffs are residents of Oklahoma.

³The comparative failure rate is disputed by Omni. According to Omni, the failure rate of the Apex Hip is 3.38 percent while the 0.27 percent figure relates to a different type of failure than the one alleged to occur in the Apex Hip. Omni also contends that recent, more comprehensive studies in 2007 show an average relevant failure rate in competing models at a rate of 6.4 percent, demonstrating that "[t]he Apex hip has a higher survival rate than reported in this industry standard reference and is well within the range of failures

replacements (and those of the members of the proposed class) have not failed or experienced other problems.

DISCUSSION

To survive a motion to dismiss, a complaint must allege "a plausible entitlement to relief." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 559 (2007), disavowing Conley v. Gibson, 355 U.S. 41, 45-46 (1957). "While a complaint attacked by a Rule 12(b)(6) motion does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Id. at 555 (internal citations and quotations omitted). See also Rodriguez-Ortiz v. Margo Caribe, Inc., 490 F.3d 92, 95 (1st Cir. 2007). Dismissal for failure to state a claim will be appropriate if the pleadings fail to set forth "factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory." Berner v. Delahanty, 129 F.3d 20, 25 (1st Cir. 1997), quoting Gooley v. Mobil Oil Corp., 851 F.2d 513, 515 (1st Cir. 1988). In deciding a Rule 12(b)(6) motion, the court may also look to documents, the authenticity of which are not disputed by the parties, to documents central to the plaintiffs' claims, and to documents referenced in the complaint. Watterson v. Page, 987 F.2d 1, 3 (1st Cir. 1993).

Choice-of-Law

As a preliminary matter, the parties disagree about the applicable state law. A federal court sitting in diversity applies the choice-of-law framework of the forum state. <u>See</u>

reported in these two [studies]." Reply at 9 n.1. This argument relies on materials that fall outside the permissible scope of consideration on a Rule 12(b)(6) motion.

Klaxon Co. v. Stentor Elec. Mfg. Co., 313 U.S. 487, 496 (1941). Under Massachusetts choice-of-law rules, tort claims are governed by the law of the state in which the injury occurred, unless another state has a more significant relationship to the underlying cause of action. Bergin v. Dartmouth Pharm., Inc., 326 F. Supp. 2d 179, 183 (D. Mass. 2004), citing Dunfey v. Roger Williams Univ., 824 F. Supp. 18, 21 (D. Mass. 1993). See Cohen v. McDonnell Douglas Corp., 389 Mass. 327, 333-334 (1983) (citation omitted) ("The place where the injury occurred is the place where the last event necessary to make an actor liable for an alleged tort takes place."). See also Pevoski v. Pevoski, 371 Mass. 358, 359-360 (1976) ("[T]here also may be particular issues on which the interests of lex loci delicti are not so strong . . . [and] another jurisdiction may sometimes be more concerned and more involved with certain issues than the State in which the conduct occurred.").

Omni argues that the court should apply Oklahoma rather than Massachusetts law because the named plaintiffs are Oklahoma residents and all of the relevant transactions and occurrences took place in Oklahoma where plaintiffs underwent their hip replacement surgery. Omni also claims prejudice in the fact that Oklahoma law requires a showing of an "actual injury," while Massachusetts law is arguably "unsettled" on the point. Omni finally asserts that Massachusetts and Oklahoma would apply different statutes of limitations to plaintiffs' claims (although it makes no argument that plaintiffs' claims would be time-barred under the laws of either state).

Plaintiffs respond that under either Massachusetts or Oklahoma choice-of-law principles, Massachusetts law applies.⁴ In a product defect class action, plaintiffs argue

⁴"A federal court sitting in diversity need not make a finding regarding which state's law is to be applied where the case's resolution would be identical under either state's law."

that the deciding factor is the manufacturer's location because it provides a hub linking the spokes of the proposed class. Here, Omni is incorporated in Massachusetts where it also has its headquarters and principal place of business. See Hertz Corp. v. Friend, 2010 WL 605601, at *11 (U.S. Feb. 23, 2010) (""[P]rincipal place of business' is best read as referring to the place where a corporation's officers direct, control, and coordinate the corporation's activities. It is the place that Courts of Appeals have called the corporation's 'nerve center.""). Plaintiffs also cite a recent Oklahoma Supreme Court case, Cuesta v. Ford Motor Co., 209 P.3d 278, 285 (Okla. 2009), that holds that the law of the domicile state of the manufacturer is controlling in a defective product class action. Finally, plaintiffs argue that the locus of the tort is properly Massachusetts as it is the forum where the design and manufacture of the allegedly defective Apex Hip took place.

The court need not probe too deeply into the differences – such as they are – between the law of Oklahoma and Massachusetts on the subject because it is as plain as a pikestaff that Massachusetts' interest in regulating the conduct of businesses operating under its laws trumps any interest that Oklahoma might have. If this case were to achieve class action status, some 1,500 class members representing all fifty states would be affected. It stands to reason that among this geographically diverse group, Massachusetts is the only state that would have a substantive tie to all of the class members. See Cuesta, 209 P.3d at 285 ("[W]e find that the law of Michigan, the state of Ford's principal place of business as manufacturer which controlled the specifications, requirements and testing for the pedals, has a greater 'intensity of interest' than any other state involved. Its law should

Fratus v. Republic Western Ins. Co., 147 F.3d 25, 28 (1st Cir. 1998).

be applied.").

The Element of Injury

"[P]urely economic losses are unrecoverable in tort and strict liability actions in the absence of personal injury or property damage." FMR Corp. v. Boston Edison Co., 415 Mass. 393, 395 (1993). Count II alleges that Omni breached contracts between it and the purchasers of the Apex Hip; contracts of which plaintiffs claim to be the intended, third-party beneficiaries. While Count II is styled as a contract claim, "couching [tort] allegations in terms of breach of contract . . . does not change the prohibition." Id. at 396 (citations omitted).⁵

Omni argues that all Counts of the Complaint should be dismissed because no legally cognizable injury is pled in any of plaintiffs' claims. See Rule v. Fort Dodge Animal

⁵If the court were to consider Count II as a contract claim it would fail for the reason that it omits the essential elements of a contract action. "A breach of contract complaint must allege (1) the existence of a valid and binding contract; (2) that plaintiff has complied with the contract and performed his own obligations under it; and (3) breach of the contract causing damages." Persson v. Scotia Prince Cruises, Ltd., 330 F.3d 28, 34 (1st Cir. 2003), citing 5 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1235, at 268-270 (2d ed. 2002). As Omni points out, plaintiffs have not alleged the existence of a contract, or even named the parties to the alleged agreement. Plaintiffs for their part argue that the Apex Hips were not being given away for free and that Omni must have had a contract of sale with someone (hospitals, surgeons, surgical centers, or health insurance companies) for which they were the intended third-party beneficiaries. See Compl. ¶ 101. Plaintiffs rely solely on an opinion of this court, Brown v. Quest Diagnostics, LLC, 2008 WL 5236033 (D. Mass. Dec. 16, 2008) (Stearns, J.), for the proposition that an "allegation that plaintiff was [an] intended third-party beneficiary of [a] contract [was] sufficient to withstand [a] motion to dismiss, even where defendant denied [the] contract existed." Opp'n at 21, citing 2008 WL 5236033, at *3. Brown is inapposite. While the court expressed skepticism whether Brown was in fact an intended third-party beneficiary, Brown at least was able to identify a supposed contractual agreement. See Reed v. Gen. Implement Export Corp., 9 F.R.D. 182, 183 (N.D. Ohio 1949) ("An oral contract, by its very nature, requires specific identification in pleading as to time, place and parties or agents. In an action on a written contract these facts would be readily ascertainable by reference to an attached copy and, where there is no copy, they should appear in the complaint.").

Health, Inc., 604 F. Supp. 2d 288, 304 (D. Mass. 2009) (Woodlock, J.) ("It is necessary for a private plaintiff to show that the defendants' deceptive act caused some form of compensable loss. . . . [Plaintiffs] ha[ve] already received the full benefit of the bargain [they] anticipated when [they] purchased [the product]"). The rule of Rule applies with the same force in consumer protection actions as it does in breach of warranty cases. See lannacchino v. Ford Motor Co., 451 Mass. 623, 634 (2008) ("As is true of a claim under G.L. c. 93A, a claim of breach of warranty requires plaintiffs to show that a defendant's conduct has caused them a loss or injury.").

Plaintiffs' stopgap argument is based on a benefit of the bargain theory. Citing <u>lannacchino</u>, plaintiffs claim that an accident-related injury or a manifested defect need not be shown as a predicate of recovery. They claim that their injuries consist of (1) the apprehension caused by the prospect of an increased risk of hip failure and (2) the extra money that they paid for an overvalued Apex Hip.⁶ In both <u>lannacchino</u> and <u>Rule</u>, all claims were dismissed because plaintiffs failed to allege a cognizable injury. In <u>lannacchino</u>, the automobile manufacturer was alleged to have produced faulty door latches, while in <u>Rule</u> heart worm medication for dogs was alleged to be less effective than advertised. Although factual distinctions can be made (<u>Rule</u> did not involve a risk of future harm and <u>lannacchino</u> involved no reported product failures), the essential point of similarity is that plaintiffs

⁶Plaintiffs also argue "future injury" in the not yet materialized costs of new hip replacements and additional surgeries, but the manifestation of these injuries would necessarily exclude putative class members actually injured from the class defined in the Complaint. See Compl. ¶ 56 ("Excluded from the Class are those persons implanted with a Defective Hip that has failed and who have been reimbursed for the product's replacement."). To the extent plaintiffs seek to represent a sub-class of persons who have experienced hip replacement failure and have not yet received reimbursement, the court finds the named plaintiffs unrepresentative of this possible sub-class.

received a product which is (to now) functioning as it was intended.

Apprehension of a heightened risk stemming from an allegedly defective product that has not failed or caused harm is insufficient as a matter of law to support a claim. See Anderson v. W.R. Grace & Co., 628 F. Supp. 1219, 1231 n.6 (D. Mass. 1986) ("The weight of authority would deny plaintiffs a cause of action solely for increased risk because no 'injury' has occurred."), cited in Rule, 604 F. Supp. 2d at 305 n.16. Plaintiffs' overpayment argument is also based on a theory of economic loss that has no place in a tort context. See lannacchino, 451 Mass. at 631, 633, citing Mass. Gen. Laws ch. 93A, § 9.

The one case plaintiffs cite that provides a modicum of support is Holtzman v. Gen. Motors Corp., 2002 WL 1923883 (Mass. Super. July 2, 2002), a Superior Court decision issued prior to lannacchino where a product liability class action with purely economic injury alleged survived a motion to dismiss. By happenstance, in lannacchino the Supreme Judicial Court adopted the Twombly heightened pleading standard. See 451 Mass. at 635. See also Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009) (the Rule 12(b)(6) pleading standard "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation."). It seems more than likely that Holtzman would have been decided differently in the wake of lannacchino.

Holtzman is also distinguishable on its facts. Plaintiffs in Holtzman were owners of automobiles alleged to be equipped with defective tire jacks. As with plaintiffs' Apex Hips, "none of the plaintiffs' jacks [had] failed, and they may never fail." Holtzman, 2002 WL

⁷Plaintiffs make no allegation in the Complaint that the Apex Hip was noncompliant with government standards. Indeed, the exhibits attached to the Complaint suggest the opposite. <u>See</u> Compl. - Ex. 1, at 7-8.

1923883, at *2. The Holtzman holding that a breach of warranty claim was sufficiently pled was based on a finding that the car jacks were "unfit for normal usage" because the products could not be used at all or "without unreasonably placing those nearby in danger of serious bodily injury." Id. By contrast, plaintiffs' hip replacements have functioned properly for from five to eleven years and, if they do fail, will not expose plaintiffs or innocent bystanders to the possibility of "injury or death." Id. at *3. Compare Compl. - Ex. 2 (failure of the Apex Hip is signaled by an "initial popping sound associated with a sense of hip instability Pain was mild to moderate All [patients] have gone on to full recovery."). As plaintiffs' claims (which include those disguised as breaches of contract) fail to plead a cognizable injury, a necessary element of a tort action, they must be dismissed.

Fraud/Concealment

Omni further argues that plaintiffs have not adequately pled fraud as required by the claims of fraudulent misrepresentation advanced in Count I (breach of implied warranty), Count III (unjust enrichment), Count IV (Chapter 93A), and Count V (other state consumer protection laws). "[A]ny claim sounding in fraud must satisfy the requirements of the heightened pleadings standard regardless of what label the pleader assigns to it." Declude, Inc. v. Perry, 593 F. Supp. 2d 290, 297 (D. Mass. 2008). "The hallmarks of fraud are misrepresentation or deceit." Ed Peters Jewelry Co., Inc. v. C & J Jewelry Co., Inc., 215 F.3d 182, 191 (1st Cir. 2000). See also Restatement (Second) of Torts § 525, at 55 (1976) ("One who fraudulently makes a misrepresentation of fact, opinion, intention or law for the

⁸See Carolet Corp. v. Garfield, 339 Mass. 75, 78 (1959) ("[T]he origins of the action on a warranty lie exclusively in tort for deceit.").

purpose of inducing another to act or to refrain from action in reliance upon it, is subject to liability to the other in deceit for pecuniary loss caused to him by his justifiable reliance upon the misrepresentation."). Under Fed. R. Civ. P. 9(b), fraudulent misrepresentation falls under a special heightened pleading requirement.⁹

Plaintiffs do not contest the fact that their misrepresentation claims sound in fraud. Rather, they maintain that Rule 9(b) has to be read in conjunction with the Rule 8 requirement that pleadings be concise and direct. In plaintiffs' view, the Complaint is sufficient to give Omni adequate notice of the fraud claims, specifically the allegation that [Omni] promoted the Defective Hip to potential purchasers of the Defective Hip, using uniform representations warranting that the Defective Hip was dependable, reliable, free from defects and of merchantable quality, or fair use and quality, and fit for its intended purpose. Compl. 27. Plaintiffs attach an article from a trade publication to the Complaint (Ex. 1) that they characterize as falsely representing "Apex's testing of the Defective Hip and confirming the integrity of the design of the Defective Hip." Compl. 29. Plaintiffs also reference a 2003 brochure distributed by Apex (Reply - Ex. A) that "asserts and/or asserted that the Defective Hip is designed to optimize stability, eliminate leg length discrepancies and facilitate alignment." Compl. 31. Plaintiffs seek to address the "who, what, when,

⁹"In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). Omni points out that the Complaint does not allege a single affirmative false statement.

¹⁰"A pleading that states a claim for relief must contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2).

¹¹As a general rule, statements of opinion and belief – so-called "seller's talk" – touting the value of a product do not constitute false representations under Massachusetts

where, how, and why," of the alleged fraud in the following fashion.

- A. Who: Apex concealed the defects described in previous paragraph regarding the Defective Hip from Plaintiffs and the Class. Plaintiffs are unaware of, and therefore unable to identify, the true names, identities and extent of liability of those individuals at Apex responsible for such decisions.
- B. What: Apex knew and fraudulent [sic] concealed or intentionally failed to disclose the material facts regarding the defects of the Defective Hip, described in the Complaint.
- C. When: Apex concealed this materials [sic] information at all times, starting no later than 1999, continuing through the time of Plaintiffs' purchase of the Defective Hip, and on an ongoing basis until the Defective Hip was redesigned.
- D. Where: Apex concealed this material information in its communications with Plaintiffs and the Class in the form of uniform representations.
- E. How: Apex concealed this material information by not disclosing it to Class Members. Apex concealed this material information even though it knew or should have known this information and knew or should have known that it would be important to a reasonable consumer in deciding whether to purchase the Defective Hip.
- F. Why: Apex concealed this material information for the purpose of inducing Plaintiffs and Class Members to purchase the Defective Hip. Had Apex disclosed the truth, Plaintiffs (and reasonable consumers) would not have purchased the Defective Hip.

Compl. ¶ 79.

Although plaintiffs make a valiant effort to comply with the formalities of Rule 9(b), they fall short on its substance. Plaintiffs' allegation that Omni knew of the alleged design defect for at least a year before the first Apex Hip was sold, and intentionally concealed it, might survive a post-<u>Twombly</u> motion to dismiss, but for the contradictory exhibits plaintiffs attach to their Complaint. <u>See</u> Compl. - Ex. 3 ("[T]hese devices were immediately

law. <u>Gaucher v. Solomon</u>, 279 Mass. 296, 299 (1932). The result may be different where an opinion is so peculiarly within the superior knowledge and expertise of its maker that a reasonable recipient would regard it as an assertion of fact. <u>Commonwealth v. Anthony</u>, 306 Mass. 470, 474-475 (1940).

discontinued from clinical use by the authors until redesigned and strength properties significantly improved."). The exhibits, rather than establishing deliberate concealment, demonstrate Omni's disclosure of testing results suggesting problems with the Apex Hip. See Compl. - Ex. 2 ("Complications still occur in [total hip arthroplasty]. One of these complications continues to be femoral component failure. This subject needs more open discussion.") (emphasis added). Another exhibit attached to the Complaint reports fatigue testing of the Apex Hip, with the carefully couched qualifier that the Apex Hip "successfully passed fatigue testing as per the relevant ISO standards and FDA guidance document." Compl. - Ex. 1, at 7. "[O]nly long-term outcome data will provide and demonstrate whether this device will improve clinical scores and survivorship." Id. at 9. See also id. at 7-8, 9 (describing a fracture to the fluted region of the stem during fatigue testing and the dislocation of two hip replacements in patients). Read in the aggregate, the court finds that Omni's alleged misrepresentations, as pled, lack "the capacity to mislead consumers, acting reasonably under the circumstances, to act differently from the way they otherwise would have acted." Aspinall v. Philip Morris Cos., Inc., 442 Mass. 381, 396 (2004). Because plaintiffs have failed to adequately allege fraud, Counts I, III, IV, and V necessarily fail on this ground as well.

<u>Unjust Enrichment</u>

Unjust enrichment is an "equitable stopgap for occasional inadequacies in contractual remedies at law." Mass. Eye & Ear Infirmary v. QLT Phototherapeutics, Inc., 412 F.3d 215, 234 (1st Cir. 2005). Under the doctrine of unjust enrichment, a plaintiff seeks restitution of a benefit conferred on another whose retention of the benefit at plaintiff's expense would be unconscionable. To satisfy the five elements of unjust

enrichment, a plaintiff must show: "(1) an enrichment, (2) an impoverishment, (3) a relation between the enrichment and the impoverishment, (4) the absence of justification and (5) the absence of a remedy provided by law." LaSalle Nat'l Bank v. Perelman, 82 F. Supp. 2d 279, 294-295 (D. Del. 2000), citing Jackson Nat'l Life Ins. Co. v. Kennedy, 741 A.2d 377, 393 (Del. Ch.1999). Plaintiffs' unjust enrichment claim fails on the fifth element because adequate remedies at law exist. Where a plaintiff has an adequate remedy at law, a claim of unjust enrichment is unavailable. See McKesson HBOC, Inc. v. New York State Common Retirement Fund, Inc., 339 F.3d 1087, 1093 (9th Cir. 2003) (Delaware law); One Wheeler Road Assocs. v. Foxboro Co., 843 F. Supp. 792, 799 (D. Mass. 1994) (Young, J.) (federal common law); Popponesset Beach Ass'n, Inc. v. Marchillo, 39 Mass. App. Ct. 586, 593 (1996) (Massachusetts law).

ORDER

For the foregoing reasons, Omni's motion to dismiss is <u>ALLOWED</u>.¹² The Clerk will enter judgment for Omni and close the case.

SO ORDERED.

/s/ Richard G. Stearns

UNITED STATES DISTRICT JUDGE

¹²The dismissal is, of course, without prejudice to the rights of any potential plaintiffs who suffer an actual failure of an implanted Apex Hip.